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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,901	03/19/2001	Jeffrey A. Hubbell	262/304US	1025,

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EXAMINER

BERMAN, SUSAN W

ART UNIT

PAPER NUMBER

1711

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,901

Applicant(s)

HUBBELL ET AL.

Examiner

Susan W Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 129-147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 129-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 13.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Response to Amendment

Amendment D, filed 04-18-2003, has been entered. The Advisory Action mailed 05-01-03 inadvertently in response to a final rejection is withdrawn since the Office Action, paper number 7, mailed 10-15-2002 was a non-final rejection.

The rejections of claims under 35 U.S.C. 112, first paragraph, or second paragraph, are withdrawn in response to the amendments of claims 1 and 139 submitted in paper number 10.

Drawings

Corrected or substitute drawings were received on 07-24-2002 and entered. These drawings are acceptable. The objection to the drawings in Figures 2b, 4, 6 7a, 7b, 11b, 12a, 12b and 13 is withdrawn in response to applicant's statement in paper number 10, page 5, that the original photos and negatives are no longer available.

Specification

The substitute specification submitted 07-24-2002 has not been entered because the claims are not the original claims filed in the application. It is noted that applicant cancelled claims 2-128 in a preliminary amendment, however, these are the claims originally filed in the specification. Applicant is required to submit the original claim pages setting forth claims 1-128 before the substitute specification can be entered.

Terminal Disclaimer

The terminal disclaimer filed on 04-18-2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent Nos. 6,258,870; 5,529,914; 5,858,746; 5,801,033 and 5,843,743 has been reviewed and is accepted. The terminal disclaimer has been recorded.

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Response to Arguments

Applicant has submitted a copy of the Declaration under C.F.R. 1.131 that was submitted in parent application no. 08/783,387, now US Patent 6,258,870, to show reduction to practice prior to the earliest filing date of the cited Soon-Shiong patents. The Declaration is considered to be insufficient to show reduction to practice of the instantly claimed invention prior to the earliest filing date of the cited Soon-Shiong patents. The data submitted in the Declaration fails to show a method of encapsulation or coating of an islet cell that is encapsulated in a microcapsule.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 129-138 are rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,700,848 or 5,705,270 or 5,846,530). See the Abstract and Examples 16-18 in US '848. Soon-Shiong teaches that the disclosed macrocapsules may contain cells that are encapsulated within microcapsules (column 9, lines 22-24, Example 26). With respect to claim 130, Soon-Shiong teaches poly(ethylene glycol), poly(amino acids), polysaccharides and proteins. Coextrusion is taught in Examples 16, 20 and 26. An accelerator to increase the rate of polymerization is taught in column 7, lines 37-49. With respect to claim 131, Soon-Shiong et al do not teach PEG tetraacrylate. However, the claim, as written, does not limit the macromer to being PEG tetraacrylate, it merely states that the PEG in the Markush group is PEG tetraacrylate.

Claims 1, 129-135 and 137-138 are rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,545,423 or 5,759,578 or 5,788,988 or 5,879,709). See the Abstract, column 7, line 43, to

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column 8, line 14, column 8, line 37, to column 9, line 14, column 11, line 64, to column 12, line 32, and Examples 5, 6 and 7 in US '423. Soon-Shiong teaches a method of microencapsulating cells such as islets and then encapsulating the microspheres in macrocapsules. With respect to claim 130, Soon-Shiong teaches polymerizable alginate, water-soluble poly(alkylene glycol), poly(amino acids), polysaccharides and proteins. An accelerator to increase the rate of polymerization is taught in column 10, lines 36-48. With respect to claim 131, Soon-Shiong et al do not teach PEG tetraacrylate. However, the claim, as written, does not limit the macromer to being PEG tetraacrylate, it merely states that the PEG in the Markush group is PEG tetraacrylate. With respect to claim 132 or 133, the claims, as written, do not limit the method of claim 3 to selection of polysaccharides or proteins from the Markush group set forth.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W Berman whose telephone number is 703 308 0040. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30. The examiner can also be reached on alternate .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck, can be reached on (703) 308 2462.

The fax phone number for the organization where this application or proceeding is assigned is 703 872 9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0661.



Susan W Berman
Primary Examiner
Art Unit 1711

S B
August 27, 2003